Regulatory benefit-risk assessment

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Stellingen behorende bij het proefschrift

Regulatory benefit-risk assessment
Different perspectives.

Arna Hrund Arnardóttir, 13 maart 2013.

1. Regulatory authorities have learned from earlier experiences in the field of HIV drugs, but whether the same applies to other drug groups has yet to be determined. – *This thesis*
2. Registrations based on limited clinical data sets have not led to additional safety risks in the past decade for drugs with high unmet medical need. – *This thesis*
3. Stakeholders in diabetes treatment have preference for antidiabetic drugs that do not negatively affect the patients' quality of life. – *This thesis*
4. Regulators are able to shift their focus from the clinical trial population to the individual patient level, showing agreement with the benefit-risk preferences of patients as well as doctors. – *This thesis*
5. The input of patients in the regulatory process could support regulatory agencies in making decisions. – *This thesis*
6. The experience of the Escher project needs to expand, making regulatory science an integral part in public health discussions.
7. "Imagine how hard it would be to achieve commercial success with new pop songs if any new song had to be better than the Beatles, if the entire Beatles catalogue was available for free, and if people did not get bored with old Beatles records" – *Scannell et.al. Drug Discovery, 2012*
8. "Unfortunately for the drug industry, doctors are not likely to start prescribing branded diabetes drugs because they are bored with generic metformin" – *Scannell et.al. Drug Discovery, 2012*
9. Everything we hear is an opinion, not a fact. Everything we see is a perspective, not the truth. – *Marcus Aurelius*
10. Drugs involve emotions– *Prof Dr P.A. de Graeff*
11. A little perspective, like a little humor, goes a long way. – *Allen Klein*
12. Sometimes words have two meanings. – *Led Zeppelin (Robert Plant)*